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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,313	08/18/2003	Atsuko Fukui	RYUK.001RE	4219
20995	7590	03/17/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			DI NOLA BARON, LILIANA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/643,313

Applicant(s)

FUKUI ET AL.

Examiner

Liliana Di Nola-Baron

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Reissue Application

1. The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following: the issue date of U.S. Patent 6,277,395 is mistakenly indicated as August 21, 2000. The correct issue date is August 21, 2001.
2. Claims 1-24 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

3. Claims 15-20 are rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material, which is not supported by the prior patent is as follows:

Claims 15-20 recite the limitation "swallowing the combination immediately after the combining step". Said limitation does not have support in the original issued patent, and the section in the issued patent pointed out by Applicant (Col. 4, lines 15-42) does not provide support for the recited limitation in claims 15-20.

Claims 19 and 20 recite the limitations "A method for swallowing a solid material, comprising the steps of:..combining the swallowing-assistive material with the solid material; wherein the solid material is enwrapped within the swallowing-assistive material". Said limitations (solid material) do not have support in the original issued patent, and the section in the issued patent pointed out by Applicant (Col. 4, lines 15-42) does not provide support for the recited limitations in claims 19-20, since said section is directed to medicines, rather than any solid material.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 15-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "swallowing the combination immediately after the combining step" in claims 15-20 represents a departure from the specification and the claims in the original issued patent, and the section in the issued patent pointed out by Applicant (Col. 4, lines 15-42) does not provide support for the recited limitation in claims 15-20.
6. Claims 19-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations "A method for swallowing a solid material, comprising the steps of: ...combining the swallowing-assistive material with the solid material; wherein the solid material is enwrapped within the swallowing-assistive material" in claims 19-20 represent a departure from the specification and the claims in the original issued patent, and the section in the issued patent pointed out by Applicant (Col. 4, lines 15-42) does not provide support for the recited limitations in claims 19-20.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speck et al.(U.S. Patent 5,010,061).

The patent discloses compositions comprising guar flour mixed with a corresponding volume of aqueous liquid and drunk within 0-5 minutes after complete mixing (See col. 3, lines 27-31), and teaches that drugs, vitamins, minerals and all kinds of contrast media can be added to the flour (See col. 3, lines 32-51). In the examples provided, the guar flour is suspended in water and drunk soon after (See Examples 1-4), or the guar flour is mixed with a medicine or contrast agent, the mixture is suspended in water and drunk soon after (See Examples 5-8). The patent teaches that the composition can be administered orally for the treatment of diseases, including intestinal peristalsis and diabetes (See col. 3, lines 32-43 and claims 1, 4-21). The patent also provides the general teaching, that indigestible polysaccharides, such as agar and guar, swell in water and form viscous jellies (See col. 1, lines 8-25).

Thus, the patent discloses drinkable compositions comprising water and a paste, which form a viscous liquid, and a medicine enwrapped in the viscous liquid, as claimed in instant claims 1, 2, 6, 7, 21 and 23, and methods for taking a medication, as claimed in instant claims 11, 13, 15, 17, 19 and 20. The patent is deficient in the sense that it does not specifically disclose the

Art Unit: 1615

viscosity range and the gel strength of the gel, however, the patent teaches that solutions of sufficiently low viscosity can be obtained by mixing the guar with water, and said solutions can be drunk (See col. 1, lines 60-62). Furthermore, it is the position of the examiner that because the patent teaches the same ingredients and same compositions as Applicant, it would flow that the invention disclosed by the patent would have the same viscosity range and gel strength as the invention claimed by Applicant. The burden is shifted to Applicant to provide evidence that the two compositions exhibit different properties, if this is the characteristic to be relied upon to show patentable distinction. Absent such an evidence, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

With regard to claims 3, 8, 22 and 24, the patent teaches that aqueous suspensions are preferred, in which the content of the guar flour is at least 2% (See col. 3, lines 67-68). Furthermore, Example 3 teaches that 4 grams of guar flour are suspended in 150 ml cold water and drunk rapidly. The mixture disclosed by the patent produces a solution of 2.6% guar and 97.4% water, which is in the range claimed by Applicant.

Regarding claims 4, 5, 9, 10, 12, 14, 16 and 18, the examples provided in the patent indicate that the guar flour is mixed with drugs, vitamins or contrast agents in solid form (See Examples 5-8). It is the position of the examiner that, due to the nature of the mixture disclosed by the patent, said drugs, vitamins or contrast agents are mixed in powder form, as claimed by Applicant.

Art Unit: 1615

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Speck et al. to device drinks to help individuals swallowing a medication, and methods for administering a medication, comprising swallowing said drinks. The expected result would have been a successful drug delivery composition and successful methods for administering drugs. Because of the teachings of Speck et al., that drugs, vitamins and contrast agents can be added to guar flour, mixed with water and drunk immediately, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful in assisting an individual in swallowing a drug. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 571-272-0592. The examiner can normally be reached on Monday through Thursday, 8:30AM-7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached at 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Application/Control Number: 10/643,313

Page 7

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

80ms3

March 9, 2004

THURMAN K. PAGE
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